

**Congress of the United States**  
**Washington, DC 20515**

March 11, 2004

The Honorable Joshua Bolten  
Director  
The Office of Management and Budget  
725 17<sup>th</sup> Street NW  
Washington, DC 20503

Dear Mr. Bolten:

We are writing about the Proposed Bulletin on Peer Review and Information Quality published in the Federal Register on September 15, 2003. As strong supporters of science in the public interest, we share the concern of the Office of Management and Budget (OMB) that federal regulatory decisions be based on the best available science. However, the current proposal has many flaws and will ensure neither sound nor timely regulatory decisions. We urge you to abandon this ill-advised plan.

The proposal's vision of scientific peer review is very different from the way peer review is conducted by professional scientists. Most scientific journals select their reviewers on the basis of scientific and technical expertise, previous publications in the journal, and prestige in their field. Reviewers often perform many reviews for the same journal, bringing to bear extensive familiarity with the scientific subject at hand. Convening and overseeing review panels is the exclusive responsibility of the journal's editorial board, all of whom are professional scientists, and is carefully controlled so as to guard the journal's scientific integrity and reputation.

The OMB's proposed bulletin departs significantly from these criteria for the selection of peer reviewers. In particular, it adopts an unsupportable distinction between conflicts stemming from federal agency funding versus private corporate funding. Potential reviewers can be disqualified if they are "currently receiving or seeking substantial funding from the [federal] agency" coordinating the review. However, there is no parallel rule to disqualify scientists whose funding comes from the regulated industry. The criteria exclude potential reviewers with "financial interests in the matter at issue," but this rule would not clearly disqualify a scientist whose research funds come from a private corporate source affected by the proposed regulation.

Furthermore, upon completion of the peer review, the OMB proposed guidelines require the report to "disclose the names, organizational affiliations, and qualifications of all peer reviewers, as well as any current or previous involvement by a peer reviewer with the agency or issue under peer review consideration." Again, the bulletin makes no mention of disclosure of peer reviewers' possible industry funding sources or other ties to corporate entities (such as board memberships, ownership of affected patents, or consulting fees) that might be affected by federal regulations based on the peer review results. Experts who have "conducted multiple peer reviews for the same agency in recent years" are also disqualified, although there is no reason to believe that if someone has assisted in previous independent peer reviews, he or she would be rendered insufficiently independent to conduct another one.

Fundamentally, departing from standard peer review procedures on the basis of an assumption that public agency funding can corrupt a reviewers' judgment but that private corporate funding cannot, is completely artificial and unconnected to reality. Professional scientific journals appropriately weigh possible conflicts of interest stemming from federal and corporate funding streams equally. For example, the peer review ethics guidelines issued by the International Committee of Medical Journal Editors state

*Reviewers must disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and they should disqualify themselves from reviewing specific manuscripts if they believe it to be appropriate.*<sup>1</sup>

No distinction is drawn between public and private funding as sources for conflicts of interest.

It is worth noting that when it comes to the biases of the authors of the articles being reviewed, the trend among top scientific journals is to be more sensitive about the appearance of bias stemming from private corporate funding than from public funding. For example, the *New England Journal of Medicine*, one of the world's leading biomedical journals, requires all authors to disclose consulting fees, paid advisory board memberships, lecture fees when speaking at the invitation of a commercial sponsor, and any grant money received from industry. Authors are not asked to disclose any funding or other ties to government agencies. The journal *Nature*, one of the world's leading general science journals, requires authors to disclose any grants they receive from "organizations that may gain or lose financially through publication of the paper".<sup>2</sup> Authors are not required to disclose funds from public grants, although most authors voluntarily include this information in the text of published articles.

The OMB bulletin also departs from standard professional scientific practice by disqualifying any reviewers who have "in recent years advocated a position on the specific matter at issue". The definition of what constitutes advocating a position is unclear. The proposal further indicates that if a reviewer who "is or appears to be biased" must be selected "in order to obtain a panel with appropriate expertise," an additional reviewer with a "contrary bias" must also be selected whether or not that person's scientific views are on the margin. Peer reviewers for professional scientific journals frequently advocate positions on scientific issues as they analyze and publish their scientific data. Many also advocate policy positions based on their scientific conclusions and/or personal convictions. Yet professional scientific journals do not disqualify them from peer review panels on this basis, nor do they seek to include extra reviewers with a "contrary bias". Peer review is intended to ensure that the science is accurate and widely respected, whether or not the reviewers have biases. Trying to balance biases without regard to the scientific views of the reviewer will undoubtedly lead to results that wander from the principle of scientific consensus that peer review strives to achieve.

Read in conjunction with your proposed requirement that only public funding, not private, be disclosed, the result you seem to be striving for is the disqualification of reviewers who do public work for their government, leaving only reviewers who assist in the profit-making

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<sup>1</sup> See <http://www.icmje.org/#peer> .

<sup>2</sup> See <http://www.nature.com/nature/submit/policies/competing/index.html> .

enterprises of particular companies. This is not a neutral approach. A neutral approach would simply require the disclosure by reviewers of all potential sources of conflict, public or private.

Finally, the proposal places ultimate control of the federal peer review process in the hands of the Office of Information and Regulatory Affairs (OIRA) within OMB. This office would decide which information would receive peer review and which would not, and rule on the acceptability of agencies' peer review processes. While OIRA has authority over federal information management, its desk officers are rarely scientists and certainly not specialists in all scientific fields reviewed by federal agencies. Control over the peer review process at scientific journals is the province of the scientific experts who make up the journal's editorial board, who have extensive professional experience in the field. Publishers, financiers and other non-scientists connected with scientific journals are not permitted oversight of or input into the journal's peer review process. Giving OIRA ultimate control over all federal peer review runs the risk of politicizing and distorting science.

The proposal clearly recognizes the validity of scientific journal peer review, stating that "for purposes of this Bulletin, peer review undertaken by a scientific journal may generally be presumed to be adequate." This makes the differences between the proposal and accepted scientific practice all the more glaring. The National Academies, composed of the nation's premier scientists, engineers and doctors who have participated in scientific peer review for their entire professional careers, have closely examined the issue of scientific peer review in federal agencies. In his comments on the bulletin submitted to OMB, National Academy of Sciences President Bruce Alberts said

*[T]he highly prescriptive type of peer review that OMB is proposing differs from accepted practices of peer review in the scientific community, and if enacted in its present form is likely to be counterproductive.<sup>3</sup>*

In light of the scope of this proposal and the extensive differences between this vision of federal and professional scientific peer review, we ask that you answer the following questions:

1. Does OMB know of situations in which current federal peer review policies produced distorted or inaccurate reviews? If so, please provide examples. If not, why is OMB attempting to fix a problem that apparently does not exist?
2. Does OMB consider funding from federal agencies a more serious source of bias than funding from private sources? If so, why?
3. Does OMB consider other, non-funding links to federal agencies a more serious source of bias than non-funding links to private sources, such as consulting fees, speaking fees, or paid service on advisory boards? If so, why?
4. Why would OMB require peer reviewers to disclose links to federal agencies, but not to companies and industries potentially affected by regulatory decisions based on the peer reviewed science?

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<sup>3</sup> See <http://www.whitehouse.gov/omb/inforeg/2003iq/115.pdf>.

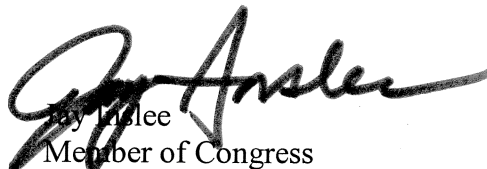
5. Would OMB's proposal disqualify a potential peer reviewer whose research funding comes from an industry potentially affected by regulations based on the outcome of the peer review? If not, why not?
6. Under this proposal, how would OMB ensure that a scientist employed by a private company potentially affected by a peer review process is automatically excluded from serving on that panel? Would such employment constitute a "financial interest in the matter at issue" as per the selection criteria? If not, why not?
7. Why does OMB believe that conducting multiple reviews for the same agency could compromise a reviewer's objectivity and be a basis for disqualification?
8. What form of advocacy does OMB envision as a disqualification for a potential peer reviewer: a scientific publication, a policy statement, a media interview, or something else? In order to determine such advocacy, will OMB require agencies to do background research on the political positions taken by potential reviewers?
9. Would a position advocated by a private company on a specific "matter at issue" exclude any potential peer reviewer employed or funded by that company? If not, why not?
10. What form of "bias" does OMB envision in the selection of reviewers? Is a scientific opinion based on peer-reviewed and rigorous scientific data considered bias? Does OMB intend to conduct reviews of bias or to direct agencies to compile information on the "biases" of their potential reviewers?
11. How much control will the Administrator of OIRA have over the selection of peer review panels and the selection of which science must be reviewed? How will OMB and OIRA prevent redundant review of previously published science? Will the OIRA Administrator override panel selections by individual agencies, even when those agencies have more expertise in the science considered and thus the suitability of individual reviewers?


Given the nature and severity of these differences, we believe that it is unlikely that minor changes will make the proposal acceptable. We urge OMB to withdraw the current proposal and develop a new one which is more in concord with professional scientific peer review practices and is informed by the conclusions of the National Academies' careful examination.

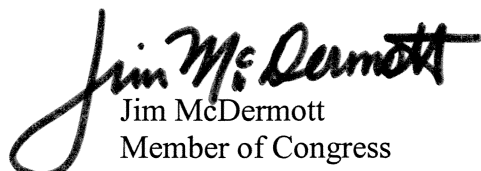
We appreciate your attention to this important matter, and look forward to a response to our questions by April 15, 2004. If you have any questions, please contact Dr. Colin McCormick (Markey) at 202-225-2836 or Ms. Michele Koppes (Inslee) at 202-225-6311.

Sincerely,

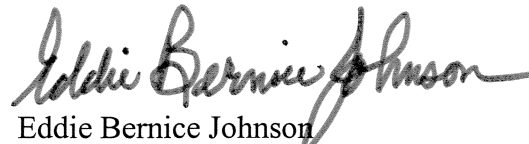
  
Edward J. Markey  
Member of Congress

  
Jay Inslee  
Member of Congress


  
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